JU 3762/5

PATENTS

HE UNITED STATES PATENT AND TRADEMARK OFFICE

| In re A | application of: |) | |
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| Cham | et al. |) | Aut I Juite 2762 |
| Serial | No. 09/879,002 |) | Art Unit: 3762 |
| Filed: | June 12, 2001 |) | Examiner: Bianco, Patricia |
| For: | Treatment for Cardiovascular and Related Diseases |) | |

FOURTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

CERTIFICATE OF MAILING

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Matthew L. Collins

Sir:

The citation of information on the attached Form PTO/SB/08 is made pursuant to 37 C.F.R. §§ 1.56, 1.97, and 1.98. A copy of each Non-U.S. Patent cited item is enclosed.

As this Supplemental Information Disclosure Statement is being filed after the issuance of an office action in the merits, pursuant to 37 C.F.R. § 1.97(c)(2), the fee of \$180.00 as set forth in § 1.17(p), is enclosed. The Commissioner is authorized to charge any additional fees that may be due or credit any overpayment to Deposit Account No. 11-0855.

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U.S. Patent Application No. 09/879,002 Fourth Supplemental Information Disclosure Statement

Respectfully submitted,

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Our Docket: 13131-0110 (44378/232454)

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE rsons are required to respond to a collection of information unless it contains a valid OMB control number Under the Paperwork ReductionA

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INFORMATION DISCLOSU STATEMENT BY

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Sheet 1 of 4

| Complete if Known | | | |
|------------------------|---------------------------|--|--|
| Application Number | 09/879.002 | | |
| Filing Date | June 12, 2001 | | |
| First Named Inventor | Cham | | |
| Group Art Unit | 3762 | | |
| Examiner Name | Bianco, Patricia | | |
| Attorney Docket Number | 13131-0110 (44378/232454) | | |

| | U.S. PATENT DOCUMENTS | | | | | |
|--|-----------------------|---|---|--|---|--|
| Examiner Initials | Cite No.1 | U.S. Patent Document Kind Code ² Number (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | |
| unuais | 1 | 3,983,008 | Shinozaki et al. | 09-28-1976 | | |
| | 2 | 3,989,466 | Pan | 11-02-1976 | 2 T. A. S. P. V. | |
| ······································ | 3 | 4,124,509 | Iijima et al. | 11-07-1978 | | |
| | 4 | 4,234,317 | Lucas et al. | 11-18-1980 | | |
| | 5 | 4,399,217 | Holmquist et al. | 08-16-1983 | | |
| | 6 | 4,402,940 | Nose et al. | 09-16-1983 | | |
| | 7 | 4,435,289 | Breslau | 03-06-1984 | | |
| | 8 | 4,463,988 | Bouck et al. | 08-07-1984 | | |
| | 9 | 4,522,809 | Adamowicz et al. | 06-11-1985 | | |
| | 10 | 4,540,401 | Marten | 09-10-1985 | | |
| | 11 | 4,613,501 | Horowitz | 09-23-1986 | | |
| | 12 | 4,615,886 | Purcell et al. | 10-07-1986 | | |
| | 13 | 4,643,718 | Marten | 02-17-1987 | | |
| | 14 | 4,671,909 | Torobin | 09-09-1987 | | |
| | 15 | 4,676,905 | Nagao et al. | 06-30-1987 | | |
| | 16 | 4,677,057 | Curtiss et al. | 06-30-1987 | | |
| | 17 | 4,775,483 | Mookerjea et al. | 10-04-1988 | | |
| | 18 | 4,832,034 | Pizziconi et al. | 05-23-1989 | | |
| | 19 | 4,836,928 | Aoyagi et al. | 06-06-1989 | | |
| | 20 | 4,909,942 | Sato et al. | 03-20-1990 | | |
| | 21 | 4,970,144 | Fareed et al. | 11-13-1990 | | |
| | 22 | 5,026,479 | Bikson et al. | 06-25-1991 | | |
| | 23 | 5,089,602 | Isliker et al. | 02-18-1992 | | |
| | 24 | 5,126,240 | Curtiss | 03-30-1992 | | |
| | 25 | 5,128,318 | Levine et al. | 07-07-1992 | | |
| | 26 | 5,152,743 | Gorsuch et al. | 10-06-1992 | | |
| | 27 | 5,187,010 | Parham et al. | 02-16-1993 | | |
| | 28 | 5,211,850 | Shettigar et al. | 05-18-1993 | | |
| | 29 | 5,236,644 | Parham et al. | 08-17-1993 | | |
| | 30 | 5,256,767 | Salk et al. | 10-26-1993 | | |
| | 31 | 5,258,149 | Parham et al. | 11-02-1993 | | |
| | 32 | 5,301,694 | Raymond et al. | 04-12-1994 | | |
| | 33 | 5,401,466 | Foltz et al. | 03-28-1995 | | |
| | 34 | 5,418,061 | Parham et al. | 05-23-1995 | | |
| • | 35 | 5,476,715 | Otto | 12-19-1995 | · · · · · · · · · · · · · · · · · · · | |
| | 36 | 5,496,637 | Parham et al. | 03-05-1996 | | |
| 2 | 37 | 5,634,893 | Rishton | 06-03-1997 | | |
| • | 38 | 5,637,224 | Sirkar et al. | 06-10-1997 | | |

| Examiner | Date | |
|-----------|------------|--|
| Signature | Considered | |

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DESCLOSUSE
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Filing Date June 12, 2001

First Named Inventor Cham

Group Art Unit 3762

Examiner Name Bianco, Patricia

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Sheet 2 of 4

| | | | | U.S. PATENT DOCUMENT | | |
|----------------------|--------------|-----------------------|-----------------------------------|---|--|--|
| Examiner Initials | Cite No.1 | U.S. Patent Number | Kind Code ² (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear |
| | 39 | 5,652,339 | | Lerch et al. | 07-29-1997 | |
| | 40 | 5,698,432 | | Oxford | 12-16-1997 | |
| | 41 | 5,707,673 | | Prevost et al. | 01-13-1998 | |
| | 42 | 5,719,194 | | Mann et al. | 02-17-1998 | |
| | 43 | 5,753,227 | | Strahilevitz | 05-19-1998 | |
| | 44 | 5,853,725 | | Salk et al. | 12-29-1998 | |
| | 45 | 5,855,782 | | Falkenhagen et al. | 01-05-1999 | |
| | 46 | 5,858,238 | | McRea et al. | 01-12-1999 | |
| | 47 | 5,877,005 | | Castor | 03-02-1999 | |
| | 48 | 5,885,578 | | Salk et al. | 03-23-1999 | |
| | 49 | 5,895,650 | | Salk et al. | 04-20-1999 | |
| | 50 | 5,911,698 | | Cham | 06-15-1999 | |
| | 51 | 5,916,806 | | Salk et al. | 06-29-1999 | |
| | 52 | 5,919,369 | | Ash | 07-06-1999 | |
| | 53 | 5,928,930 | | Salk et al. | 07-27-1999 | |
| | 54 | 5,948,441 | | Lenk et al. | 09-09-1999 | |
| | 55 | 5,962,322 | | Kozarsky et al. | 10-05-1999 | |
| | 56 | 6,017,543 | | Salk et al. | 01-25-2000 | |
| | 57 | 6,022,333 | | Kensev | 02-28-2000 | |
| | 58 | 6,037,458 | | Hirai et al. | 03-14-2000 | |
| | 59 | 6,039,946 | | Strahilevitz | 03-21-2000 | |
| | 60 | 6,309,550 | | Iverson et al. | 10-30-2001 | |

Attorney Docket Number

| | | | | FORE | IGN PATENT DOCUMEN | ITS | | |
|----------------------|--------------|---------------------|--------------------------------------|--|--|--|--|----------------|
| Examiner Initials | Cite No.1 | Office ³ | Foreign Patent [Number ⁴ | Oocument Kind Code ⁵ (if known) | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Т ⁶ |
| | 61 | CA | 1 271 708 | | Schweiz Serum & Impfinst | 07-17-1990 | | |
| | 62 | CN | 1189378 | | Central Blood Ban ChangChun CI | 08-05-1998 | Abstract Only | |
| | 63 | DE | 33 10 263 | A1 | Fresenius AG | 09-27-1984 | | |
| | 64 | SU | 1752187 | A3 | Sigalov | 07-30-1992 | Abstract only | |
| | 65 | WO | 88/09345 | A1 | The Rogosin Institute | 12-01-1988 | | |
| | | | | | | | | |
| | | | | | | | | \blacksquare |

| Examiner Signature | Date Considered | |
|-----------------------|--------------------|--|

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Under the Paperwork Reduction

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INFORMATION DISC STATEMENT BY AFR

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Sheet 4 of | 4

| Complete if Known | | | | | |
|--------------------------------|---------------------------|--|--|--|--|
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| Examiner Name Bianco, Patricia | | | | | |
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| | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the | |
|----------------------|--------------|---|---|
| Examiner Initials | Cite No.1 | item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T |
| | 79 | Ngu, Medical Hypotheses, Human Cancers and Viruses: A Hypothesis for Immune Destruction of Tumours Caused by Certain | |
| | | Enveloped Viruses Using Modified Viral Antigens, 39, 17-21. (1992) | |
| | 80 | Ngu, Medical Hypotheses, The viral envelope in the evolution of HIV: a hypothetical approach to inducing an effective immune | |
| | | response to the virus, 48, 517-521. (1997) | |
| | 81 | Okazaki et al., Journal of Chromatography, Biomedical Applications, Improved High-Performance Liquid Chromatographic | |
| | | Method for the Determination of Apolopoproteins in Serum High-Density Lipoproteins, 430, 135-142. (1988) | |
| | 82 | Robern et al., Experientia, The Application of Sodium Deoxycholate and Sephacryl-200 for the Delipidation and Separation of | |
| | | High Density Lipoproteins, 38, 437-439. (1982) | |
| | 83 | Scanu et al., Analytical Biochemistry, Solubility in Aqueous Solutions of Ethanol of the Small Molecular Weight Peptides of the | |
| | | Serum Very Low Density and High Density Lipoproteins: Relevance to the Recovery Problem During Delipidation of Serum | |
| | | Lipoproteins, 44, 576-588. (1971) | |
| | 84 | Williams et al., Biochim. Biophys. Act., Uptake of Endogenous Cholesterol by a Synthetic Lipoprotein , 875 (2), 183-194. | |
| | | (February 12, 1986) | |
| | | | |
| | | | |
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Considered

PTO/SB/08B (08-00)

Approved for use through 10/31/2002 OMB 0651-0031 U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/A/PTO

INFORMATION DISCLOSURES

(use as many sheets as necessary

Sheet 3 of 4

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|-------------------------------|---------------------------|--|--|--|
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| | | OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS | |
|----------------------|--------------|--|----|
| Examiner Initials | Cite No.1 | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T' |
| | 66 | Asztalos et al., Arterioscler. Thromb. Vasc. Biol., Presence and Formation of 'Free Apolipoprotein A-I-Like' Particles in Human | |
| | | Plasma, 15, 1419-1423, . (1995) | |
| | 67 | Asztalos et al., Arterioscler. Thromb. Vasc. Biol., Role of Free Apolipoprotein A-l in Cholesterol Efflux, 17, 1630-1636. (1997) | |
| | 68 | Barrans et al., Biochimica et Biophysica Acta, Pre-β HDL: Structure and Metabolism, 1300, 73-85. (1996) | |
| | 69 | Collet et al., Journal of Biological Chemistry, Differential Effects of Lecithin and Cholesterol on the Immunoreactivity and | |
| | | Confirmation of Apolipoprotein A-I in High Density Lipoproteins, 266 (14), 9145-9152. (May 15, 1991) | |
| | 70 | Cruzado et al., Analytical Biochemistry, Characterization and Quantitation of the Apoproteins of High-Density Lipoprotein by | |
| | | Capillary Electrophoresis, 14 (7), 100-109. (1996) | |
| | 71 | Deva, et al., J. Hosp. Infect., Establishment of an in-use testing method for evaluating disinfection of surgical instruments using | |
| | | the duck hepatitis B model , 22, 119-130. (abstract only) (June 1996) | |
| | 72 | Feinstone, et al., Infection and Immunity, Inactivation of Hepatits B Virus and Non-A, Non-B Hepatitis by Chloroform, 41, 816-821. (August 1983) | |
| | 73 | Hatch et al., Lipoprotein Analysis, Advances in Lipid Research, Practical Methods for Plasma Lipoprotein Analysis, 6, 1-68. | ĺ |
| | | (1968) | |
| | 74 | Horowitz, et al., Blood Coagulation and Fibrinolysis, Viral safety of solvent/detergent-treated blood products, 5, S21-S28. | |
| | | (1994) | |
| | 75 | Jackson et al., Biochimica et Biophysica Acta, Isolation and Characterization of the Major Apolipoprotein from Chicken High | |
| | | Density Lipoproteins, 420, 342-349. (1976) | |
| | 76 | Koudinov et al., Cell Biol Int., Alzheimer's Soluble Amyloid Beta Protein is Secreted by HepG2 Cells as an Apolipoprotein, 21 | T |
| | | (5), 265-71. (abstract only) (May 1997) | |
| | 77 | Moya et al., Arteriosclerosis and Thrombosis, A Cell Culture System for Screening Human Serum for Ability to Promote | |
| | | Cellular Cholesterol Efflux, 14 (7), 1056-1065. (July 1994) | |
| | 78 | Ngu, Medical Hypotheses, Chronic Infections from the Perspective of Evolution: a Hypothesis, 42, 81-88. (1994) | 1 |

| Examiner | Date |
|-----------|------------|
| Signature | Considered |

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.